

Application No. 09/614,669  
Amendment Dated: April 11, 2003  
Response to Office Action Dated February 19, 2003

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This listing of claims will replace all prior versions and listings of claims in the above-identified application

1. (Currently Amended) A method of enhancing and/or prolonging [the] a response [of] to a primary challenge to a responsive system comprising the steps of:
- a) subjecting a test site[, as defined herein,] of the responsive system to the primary challenge;
  - b) subjecting the test site to a secondary challenge, wherein the secondary challenge differs from the primary challenge and wherein the secondary challenge is designed to enhance, and/or prolong [a] the response of the responsive system to the primary challenge; and
  - c) assessing the response using a means selected from the group consisting of visual evaluation using a predefined scale and TEWL;
- wherein the primary challenge is a chemical challenge and the secondary challenge is a physical challenge, [ and wherein the term "assessing" means any method of evaluating, observing, noting, and/or comparing the condition (e.g., response) of test sites] the physical challenge being selected from the group consisting of heat, cold, humidity, desiccation, tape stripping, friction, abrasion, lubrication, pressure, vacuum, occlusion, sound and combinations thereof.
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- see page 13*
- OK*
- see page 8*

Claims 2-4 (Canceled)

- 5. (Original) The method according to Claim 1 further comprising the steps of subjecting the test site to at least one pre-challenge intervention.
- 6. (Original) The method according to Claim 1 further comprising the steps of subjecting the test site to at least one intervention selected from the group consisting of concurrent-challenge intervention, post-challenge intervention, and mixtures thereof.
- 7. (Currently Amended) The method according to Claim 1 wherein assessing the response comprises [visual and/or] TEWL measurement.
- 8. (Currently Amended) A study [of enhancing and/or prolonging the] utilizing enhanced and/or prolonged responses [of] to a primary challenge to a responsive system comprising the steps of:
  - a) applying the primary challenge to a test site[, as defined herein,] of the responsive system; applying a secondary challenge to the test site, wherein

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the secondary challenge differs from the primary challenge and wherein the secondary challenge is designed to enhance and/or prolong a response of the responsive system to the primary challenge, wherein the primary challenge is a chemical challenge and the secondary challenge is a physical challenge that is selected from the group consisting of heat, cold, humidity, desiccation, tape stripping, friction, abrasion, lubrication, pressure, vacuum, occlusion, sound and combinations thereof; and

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- b) creating one or more controls selected from the group consisting of negative controls, primary controls, secondary controls, positive controls, and mixtures thereof;
  - c) assessing a primary challenge response subsequent to the primary challenge and prior to the secondary challenge using a means selected from the group consisting of visual evaluation using a predefined scale and TEWL;
  - d) assessing [one or more] at least one secondary challenge response[s] one or more times after the secondary challenge using a means selected from the group consisting of visual evaluation using a predefined scale and TEWL;
  - e) assessing [one or more] at least one control response[s] to the controls at the same approximate times as the primary challenge assessment and secondary challenge assessments are made using a means selected from the group consisting of visual evaluation using a predefined scale and TEWL;
  - f) drawing conclusions based upon the assessments[, wherein the term "assessing" means any method of evaluating, observing, noting, and/or comparing the condition (e.g., response) of test sites].

- 9. (Canceled)
- 10. (Original) The study according to Claim 8 comprising at least one additional step comprising subjecting the test site and/or one or more controls to at least one pre-challenge intervention.
- 11. (Original) The study according to Claim 8 comprising at least one additional step selected from the group consisting of subjecting the test site and/or one or more controls to at least one concurrent-challenge intervention, and/or subjecting the test site and/or the one or more controls to at least one post-challenge intervention.
- 12. (Canceled)

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13. (Previously Amended) The method according to Claim 1 wherein the secondary challenge is tape-stripping.
  14. (Previously Amended) The method according to Claim 1 wherein the primary challenge comprises more than one component and/or step.
  15. (Previously Amended) The method according to Claim 1 wherein the chemical challenge is applied to the test site via a patch.
  16. (Currently Amended) The method according to Claim 15 wherein the test site is skin [and/or cell cultures derived therefrom].
  17. (Previously Amended) The method according to Claim 16 wherein the chemical challenge comprises applying stool and/or stool analog.
  18. (Original) The method according to Claim 17 wherein the test site is subject to the primary challenge for up to about 24 hours.
  19. (Original) A clinical study designed to assess affects of chemicals on preventing and/or treating diaper rash comprising the method according to Claim 16.
  20. (Previously Amended) The method of Claim 17 wherein the test site is an adult's forearm and the primary challenge is stool.
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